

Immunoglobulin G FS*

Diagnostic reagent for quantitative in vitro determination of immunoglobulin G (IgG) in serum or plasma on BioMajesty JCA-BM6010/C

Order Information

Cat. No. 1 7212 99 10 964

R1: 6 x 90 tests

R2: 6 x 90 tests

Method

Immunoturbidimetric test

Principle

Determination of the IgG concentration by photometric measurement of antigen-antibody-reaction between antibodies to human IgG and IgG present in the sample.

Reagents

Components and Concentrations

R1:	TRIS	pH 7.5	100 mmol/L
	NaCl		150 mmol/L
R2:	TRIS	pH 8.0	100 mmol/L
	NaCl		300 mmol/L
	Anti-human IgG antibody (goat)		< 1%

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
- Reagent 2 contains animal material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [8].
- Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
- For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent trays.

Specimen

Serum, heparin plasma or EDTA plasma

Stability [1]:

3 months	at	20 – 25°C
3 months	at	4 – 8°C
6 months	at	-20°C

Only freeze once! Discard contaminated specimens.

Calibrators and Controls

For calibration the DiaSys TruCal Protein calibrator set is recommended. The assigned values of the calibrators have been made traceable to the reference material ERM®-DA470k/IFCC. For internal quality control DiaSys TruLab Protein controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal Protein (5 levels)	5 9200 99 10 039	5 x 1 mL
TruLab Protein Level 1	5 9500 99 10 046	3 x 1 mL
TruLab Protein Level 2	5 9510 99 10 046	3 x 1 mL

Performance Characteristics

Measuring range up to 3200 mg/dL (214 µmol/L) IgG, at least up to the concentration of the highest calibrator (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or rerun function).	
Limit of detection**	1 mg/dL (0.07 µmol/L) IgG
No prozone effect up to 8000 mg/dL (534 µmol/L) IgG	
On-board stability	6 weeks
Calibration stability	4 weeks

Interferences < 10% by
Conjugated Bilirubin up to 60 mg/dL
Unconjugated Bilirubin up to 60 mg/dL
Hemoglobin up to 900 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
No cross reaction with IgA and IgM was observed.
For further information on interfering substances refer to Young DS [7].

Precision			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	925	986	2366
Mean [µmol/L]	61.7	65.8	158
Coefficient of variation [%]	2.01	1.54	1.20
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	906	1691	2327
Mean [µmol/L]	60.4	113	155
Coefficient of variation [%]	2.75	2.58	2.37

Method comparison (n=51)	
Test x	Competitor Immunoglobulin G
Test y	DiaSys Immunoglobulin G FS
Slope	1.015
Intercept	-16.6 mg/dL (-1.11 µmol/L)
Coefficient of correlation	0.998

** lowest measurable concentration which can be distinguished from zero mean + 3 SD (n = 20) of an analyte free specimen

Conversion factor

IgG [mg/dL] x 0.067 = IgG [µmol/L]



Reference Range

Adults [2]	700 – 1600 mg/dL	46.9 – 107 µmol/L
Children [3]	Newborns	700 – 1600 mg/dL
	1 – 3 month(s)	250 – 750 mg/dL
	4 – 6 months	180 – 800 mg/dL
	7 – 12 months	300 – 1000 mg/dL
	2 years	350 – 1000 mg/dL
	3 – 5 years	500 – 1300 mg/dL
	6 – 9 years	600 – 1300 mg/dL
	10 – 13 years	700 – 1400 mg/dL
		46.9 – 107 µmol/L
		16.8 – 50.3 µmol/L
		12.3 – 53.6 µmol/L
		20.1 – 67.0 µmol/L
		23.5 – 67.0 µmol/L
		33.5 – 87.1 µmol/L
		40.2 – 87.1 µmol/L
		46.9 – 93.8 µmol/L

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

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- Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
- Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanism, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240–1243.

Manufacturer
  DiaSys Diagnostic Systems GmbH
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Immunoglobulin G FS

Chemistry code 10 721

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	175
R2e volume	0
R2 volume	35
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1.0
Sample vol (U)	1.0
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Endpoint Method	
Re.absorb (u)	9.999
Re.absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.l	0
M-DET.P.m	32
M-DET.P.n	33
S-DET.P.p	17
S-DET.P.r	18
Check D.P.l.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Sub-analy. Conditions	
Name	IGG
Digits	2
M-wave L.	571
S-wave.L	****
Analy.mthd.	EPA
Calc.mthd.	MSTD
Qualit. judge	No

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Analysis Test Condition Setting (M)		
Sample Type	Serum	Urine
Reac. sample vol.	1.0	1.0
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

Prozone	
Prozone form	No
Prozone limit	9.999
Prozone judge	Upper limit
Judge limit	9.999
M-DET.P.m	0
M-DET.P.n	0
S-DET.P.p	0
S-DET.P.r	0

MULTI-STD Setting								
Formula	Logit Log 3	Axis Conv	No conv					
Blank	Blank is 0	Points	6					
	FV	Reac. smp. vol.	Dil. method	Dil. smp. vol.	Diluent vol.	Diluent pos.	STD H	STD L
BLK	#	1.0	No dil	0	0	0	9.999	-9.999
1	#	1.0	No dil	0	0	0	9.999	-9.999
2	#	1.0	No dil	0	0	0	9.999	-9.999
3	#	1.0	No dil	0	0	0	9.999	-9.999
4	#	1.0	No dil	0	0	0	9.999	-9.999
5	#	1.0	No dil	0	0	0	9.999	-9.999

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